National Veterinary Services Laboratories Scrapie/Chronic Wasting Disease Immunohistochemistry (IHC) Proficiency Test Summary

- **1.** Composition of proficiency test panel: The scrapie/CWD IHC panel consists of five (5) unstained histologic sections (formalin-fixed, paraffin embedded) of sheep/deer/elk brains/lymph nodes on glass slides.
- **2. Cost of proficiency test:** No charge to approved laboratories.
- **3. Storage conditions:** Samples are stored at room temperature (18°-26°C).
- **4. Sample preparation/selection criteria:** Samples selected are from various samples submitted from field suspect cases of scrapie/CWD. These selected samples are tested by IHC and vary from positive to weakly positive to negative for the presence of prion protein.
- **5. Panel quality control:** All slides are cut at one time. The NVSL stains the first and last slide of the series for consistency and evaluate the staining quality and staining morphology.
- **6. Timing of the proficiency test distribution and data collection:** The PT is issued annually with a target month of June.
- **7. Test method:** The PT samples are tested by IHC staining of panel slides using approved methods. Subsequent evaluation and scoring/interpretation of the resultant staining are done by the PT participants and the slides and results are then sent to the Head of the Special Pathology Laboratory at NVSL for final evaluation.
- **8. Submitting test results:** Participants are required to have the results of staining interpretations and the stained slides submitted to the Head of Special Pathology at NVSL not later than ten (10) days after panel has been received by the participant.
- **9. Scoring of individual panel samples:** For each panel a score is based on number of slides with correct interpretation (Positive/Not Detected) by the participant. Additional dialog or training may be required if interpretations do not include the identification of inappropriate tissues locations, or if incorrect diagnostic terminology is used in reporting results.
- **10.** Laboratory pass/fail criteria: A final score of 100 percent correctly identified slides (Positive and Not Detected) is considered as a passing score.
- **11. Reporting laboratory test scores:** Panel results and slides are sent to the Head of Special Pathology, at NVSL, who will share by (e-mail/postal mail), the results with each

individual participant. Results will be shared within three (3) weeks after receipt of the results and slides from all panels.

12. Remedial actions required for failing laboratories: If discrepant results are obtained due to misinterpretation, additional training may be required. The NVSL may issue a larger pre-stained panel for interpretation and scoring. If discrepant results in the interpretation persist this may be considered grounds for withdrawal of laboratory approval.

If discrepant results are caused by suboptimal staining (or clearly suboptimal staining is observed) NVSL will work with the laboratory or other sources to determine the cause of the suboptimal staining. If it is determined to be laboratory-related and suboptimal staining persists this may be considered grounds for withdrawal of laboratory approval.

13. Special requirements: Restrictions - A USDA permit is required to obtain the controls. Failure on the part of participate laboratories to maintain current permits may result in withdrawal of approval until such time as a permit and control samples and/or PT samples can be sent.